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EXAMINER	
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3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,367	SVEHLA ET AL.	
	Examiner	**Art Unit**	
	KATHLEEN SONNETT	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-22 and 25-76* is/are pending in the application.

4a) Of the above claim(s) *38-72 and 74-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-22,25-37, and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

1. Claims 20-22 and 25-76 are pending. Claims 38-72 and 74-76 are withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 29 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 29 and 34 include the limitation "the flat surface" which lacks antecedent basis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 20-22, 25, 27, 35, 37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Blomberg (U.S. 3,738,366). Blomberg discloses a forceps tool capable of controlling an implantable electrode assembly comprising a first flexible arm (17) comprising contiguous first and second elongate regions having proximal and distal ends, the distal end of the first region being connected to the proximal end of the second region, a length of the second region (1) having a concave cross-sectional shaped region (20) wherein the proximal end of the concave-shaped cross-sectional region is configured to receive the electrode along a longitudinal axis through its geometric center since the proximal end can be considered to fall

somewhere distal of grip portion (17) and has an open end and wherein the concave shape enables the second region to receive and support the electrode such that relative movement of the electrode is permitted while relative lateral movement of the electrode is substantially restricted, and a second flexible arm (18) comprising first and second contiguous elongate regions with proximal and distal ends, the second region of the second arm having a tip region (21), wherein a longitudinal axis through the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region, and wherein the proximal end of the first region of the first arm is pivotally fixed to the proximal end of the first region of the second arm, and wherein application of a force to the first and second arms causes the tip region to be in proximity to the concave region to retain the electrode in a space defined by the concave region and the tip region.

6. Regarding claims 21 and 22, the concave region comprises a region having a substantially C-shaped cross-section. This can be considered a half-tube shaped section as well (see fig. 6).

7. Regarding claim 25, the second regions of the arms are positioned at an angle of about 0 to 25 degrees from the first regions of the first and second arms.

8. Regarding claim 27, a line through the center of the space defined by the concave region is substantially aligned with the longitudinal axis of the second region of the first arm (fig. 1).

9. Regarding claim 35, when the arms are compressed the distal ends of the second regions move toward each other.

10. Regarding claim 37, the forceps are capable of holding any of the electrode arrays listed in claim 37.

11. **Claims 20-22, 25-27, 32, 37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Baccala et al. (U.S. 4,785,810). Baccala et al. disclose a manually adjustable forceps tool capable of controlling an implantable electrode assembly comprising a first flexible arm (region distal of pin (50)) comprising contiguous first and second elongate regions (second region starting at bend) having proximal and distal ends, the second region having a concave shaped region (16) near said distal end of the second region and a second flexible arm (distal of pin (50)) comprising first and second contiguous elongate regions with proximal and distal ends, the second region of the second arm having a tip region (28) wherein the proximal end of the first region of the first arm is pivotally fixed to the proximal end of the first region of the second arm, and wherein application of a force to the first and second arms causes the tip region to be in proximity to the concave region to retain the electrode assembly in a space defined by the concave region and the tip region. The longitudinal axis of the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region and the concave region receives and supports an electrode assembly such that longitudinal movement of the electrode relative to the concave region is permitted and lateral movement of the electrode relative to the concave region is permitted.

12. Regarding claims 21 and 22, a cross section of the concave shaped region (26) will have a C-shaped cross section and substantially half-tube shaped.

13. Regarding claim 25, the second regions of the arms are at 30 degrees which is considered approximately 25 degrees (col. 5 ll. 8-13; obtuse angle of 150 degrees gives acute angle of 30 degrees).

14. Regarding claim 26, Baccala et al. disclose an angle of 18 degrees because the obtuse angle can be between 90 and 180 degrees (162 degrees gives an acute angle of 18 degrees).

15. Regarding claim 27, a line through the center of the space defined by the concave cross-sectional shaped second region is substantially aligned with the longitudinal axis of the second region of the first arm.

16. Regarding claims 32, the tip region extends the length of the second region (entire portion after bend in arm) and has an approximately constant cross-section.

17. **Claims 20-22, 27, 28, 32, 33, 35, 37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Willis et al. (US 4,759,359). Willis et al. disclose a forceps tool capable of controlling an implantable electrode assembly comprising a first flexible arm comprising contiguous first and second elongate regions, wherein the distal end of the first region is connected to the proximal end of the second region, a length of the second region comprising a concave cross-sectional shaped region (13), wherein the proximal end of the concave-shaped region is configured to receive the electrode along the a longitudinal axis of through the geometric center of the concave-shaped region and wherein the concave cross-sectional shape enables the second region to receive and support the electrode assembly such that relative longitudinal movement of the electrode is permitted while relative lateral movement of the electrode is substantially restricted and a second flexible arm comprising first and second contiguous elongate regions wherein the distal end of the first region is connected to the proximal end of the second region, the second region of the second arm having a tip region (28) wherein a longitudinal axis through the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region (see fig. 3) and wherein the proximal end of the first region of the first arm is connected to the proximal end of the first region of the second arm (where 24 and 25 meet) and wherein application of a force to at least one of the first regions causes the tip region to travel toward the concave cross-sectional shaped region and when the tip is in proximity to the concave cross-sectional shaped region, the electrode assembly is

retained in a space defined by the concave cross-sectional shaped region and the tip region, thereby providing operator control of the longitudinal movement of the electrode.

18. Regarding claims 21 and 22, the region has a substantially c-shaped cross-section.

19. Regarding claim 27, a line through the center of the space defined by the concave cross-sectional shaped second region is substantially aligned with the longitudinal axis of the second region of the first arm.

20. Regarding claim 28, the concave cross-sectional shape has an aperture (15) positioned at its trough (14).

21. Regarding claim 32, the tip region extends the length of the second region of the second arm and comprises an approximately constant cross-section.

22. Regarding claim 33, the cross section of the tip region (28) is being considered substantially rectangular.

23. Regarding claim 35, the distal ends of the second regions move towards each other when the arms are compressed and move away from each other when the compression is released.

24. Regarding claim 37, the electrode array is not positively claimed and the device is capable of being used with any of the following: a cochlea, spinal, or auditory midbrain stimulation electrode array.

25. **Claims 20-22, 27, 29, 30, 32, 34, 37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Fujitsu et al. (US 5,464,405). Fujitsu et al. disclose a manually adjustable forceps tool for controlling an implantable electrode assembly comprising a first flexible arm comprising contiguous first and second elongate regions, wherein the distal end of the first region is connected to the proximal end of the second region, a length of the second region comprising a concave cross-sectional shaped region (9), wherein the proximal end of the

concave-shaped region is configured to receive the electrode along the a longitudinal axis of through the geometric center of the concave-shaped region and wherein the concave cross-sectional shape enables the second region to receive and support the electrode assembly (inside tube 10) such that relative longitudinal movement of the electrode assembly is permitted while relative lateral movement of the electrode assembly is substantially restricted and a second flexible arm comprising first and second contiguous elongate regions wherein the distal end of the first region is connected to the proximal end of the second region, the second region of the second arm having a tip region wherein a longitudinal axis through the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region (see figs. 1-3) and wherein the proximal end of the first region of the first arm is connected to the proximal end of the first region of the second arm and wherein application of a force to at least one of the first regions causes the tip region to travel toward the concave cross-sectional shaped region and when the tip is in proximity to the concave cross-sectional shaped region, the electrode assembly is retained in a space defined by the concave cross-sectional shaped region and the tip region, thereby providing operator control of the longitudinal movement of the electrode assembly.

26. Regarding claims 21 and 22, see fig. 3.

27. Regarding claim 27, a line through the center of the space defined by the concave region is substantially aligned with the second region of the first arm.

28. Regarding claims 29, 30, 32, and 34, the tip region of 3 has an approximately half-circular cross-section with a flat surface proximate to the concave region (9). The tip region has an approximately constant cross-section. The width of the flat surface is greater than the width of the space defined by the concave region.

29. **Claims 20, 25, 27, 29, 31, 37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Fisher (US 1,653,803). Fisher discloses a forceps tool capable of controlling an implantable electrode assembly comprising a first flexible arm (12) comprising contiguous first and second elongate regions, wherein the distal end of the first region is connected to the proximal end of the second region, a length of the second region comprising a concave cross-sectional shaped region (between wings 14, 15), wherein the proximal end of the concave-shaped region is configured to receive the electrode along the a longitudinal axis of through the geometric center of the concave-shaped region and wherein the concave cross-sectional shape enables the second region to receive and support the electrode such that longitudinal movement of the electrode relative to the forceps is permitted while lateral movement of the electrode relative to the forceps is substantially restricted and a second flexible arm (11) comprising first and second contiguous elongate regions wherein the distal end of the first region is connected to the proximal end of the second region, the second region of the second arm having a tip region wherein a longitudinal axis through the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region (figs. 2, 3) and wherein the proximal end of the first region of the first arm is connected to the proximal end of the first region of the second arm (at 8) and wherein application of a force to at least one of the first regions causes the tip region to travel toward the concave cross-sectional shaped region and when the tip is in proximity to the concave cross-sectional shaped region, the electrode assembly is retained in a space defined by the concave cross-sectional shaped region and the tip region, thereby providing operator control of the longitudinal movement of the electrode.

30. Regarding claim 25, the second regions of the first and second arms are positioned at an angle of approximately 0 degrees fro the first regions of the arms (first region being proximal half of arms distal of pivot point 8).

31. Regarding claim 27, a line through the center of the space defined by the concave region is substantially aligned with the second region of the first arm.

32. Regarding claim 29, the tip region (11) comprises a region having an approximately half-circular shaped cross-section wherein the half-circular shape is proximate to the concave cross-sectional shaped region when the tip is in proximity to the concave cross-sectional shaped region (see fig. 3; flat surface of 11 rests against handle "H").

33. Regarding claim 31, a width of the tip region has a width less than the width of the space defined by the concave cross-sectional shaped region (see fig. 3).

34. **Claims 20, 27, 29, 30, 32, 34, 37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Roeschmann (US 2,887,110). Roeschmann discloses a forceps tool capable of controlling an implantable electrode assembly comprising a first flexible arm (12) comprising contiguous first and second elongate regions, wherein the distal end of the first region is connected to the proximal end of the second region, a length of the second region comprising a concave cross-sectional shaped region (23), wherein the concave cross-sectional shape enables the second region to receive and support the electrode such that longitudinal movement of the electrode relative to the forceps is permitted while lateral movement of the electrode relative to the forceps is substantially restricted and a second flexible arm (13) comprising first and second contiguous elongate regions wherein the distal end of the first region is connected to the proximal end of the second region, the second region of the second arm having a tip region wherein a longitudinal axis through the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region (figs.1, 4) and wherein the proximal end of the first region of the first arm is connected to the proximal end of the first region of the second arm (at 17) and wherein application of a force to at least one of the first regions causes the tip region to travel toward the concave cross-sectional shaped region and when the

tip is in proximity to the concave cross-sectional shaped region, the electrode is retained in a space defined by the concave cross-sectional shaped region and the tip region, thereby providing operator control of the longitudinal movement of the electrode.

35. Regarding claim 27, a line through the center of the space defined by the concave region is substantially aligned with the second region of the first arm.

36. Regarding claim 29, the tip region is being considered approximately half-circular shaped in cross-section, wherein a flat surface of the half-circular shape is proximate to the concave cross-sectional shaped region when the tip region is in proximity to the concave cross-sectional shape.

37. Regarding claim 30, the flat surface of the tip region has a width greater than the width of the space defined by the concave region.

38. Regarding claims 32 and 34, the tip region extends the length of the second region, comprises an approximately constant cross-section, and is approximately half-circular shaped in cross-section, wherein a flat surface of the tip region is proximate to the concave region.

Claim Rejections - 35 USC § 103

39. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

40. **Claims 25 and 26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Willis et al. Willis et al. disclose the invention substantially as stated above including that the second regions of the first and second arms are each positioned at a small angle relative to their first regions (see fig. 3). Willis et al. is silent on the degree of the angle.

41. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to change this angle to 18 degrees since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980)). That is, the instrument of Willis is used to grasp and insert lens material and an appropriately small bend angle allows better visualization of the end of the instrument without compromising access to smaller spaces. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Willis to choose a bend angle of 18 degrees since it would involve only routine skill in the art to find an optimum value.

42. **Claim 36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Willis et al. in view of Chester (US 3,815,607). Willis et al. discloses the invention substantially as stated above including a post (26) positioned on one of the arms proximate to the other arm when the tip region is in proximity to the concave region. Willis et al. does not expressly disclose that the post member prevents the tip region from contacting the concave region.

43. Chester teaches that posts are used to ensure that the tip regions of forceps tools remain aligned and also to prevent the application of excessive force to the device (col. 2 ll. 55-60). It would have been obvious to one skilled in the art to modify Willis to ensure that the post prevents excessive force from being delivered to the tip region of the forceps tool in order to ensure that whatever is being held between the concave region and tip region is not damaged in any way. For example, when the device of Willis is used to fold a lens prosthesis, it would have been obvious to one skilled in the art in view of Chester to provide the post in a manner that results in the concave region and tip region having enough clearance in the closed configuration to fit a prosthesis within the space without applying excessive force to the prosthesis.

Response to Arguments

44. Applicant's arguments filed 7/23/2008 have been fully considered but they are not persuasive. Applicant argues that the references of Blomberg, Baccala et al., Willis et al., Fisher, and Roeschmann fail to disclose a proximal end of a concave-shaped cross-sectional region configured to receive an electrode assembly along a longitudinal axis through the geometric center of the concave region.

45. Regarding the prior art of Blomberg, although the distal tip of this second region (concave-region) is closed (at 20), the proximal end of the second region can be considered to fall at a point distal of the roughened region (17). The second region also need not include the entire portion of the forceps arm that falls distal of the roughened region (17). This proximal end is open and can therefore receive an electrode assembly along a longitudinal axis through the geometric center of the concave region. It is not necessary that the electrode is inserted at the very proximal end (4) or distal end of the entire forceps tool. Similarly, the device of Baccala et al. and Willis et al. meet this limitation. The second region need not be considered the entire concave-shaped region of the forceps of Baccala et al. When only the distal half of region (12) is considered the second region of the forceps, the proximal end of this region is open and in line with the geometric center of the concave region and therefore free to receive an electrode assembly along the axis of the geometric center. In the case of Baccala et al., the proximal end can receive an electrode from either a proximal or distal direction since the concave region is open at both its ends. The concave region of Willis et al. can receive an electrode through its geometric center at its distal end and the electrode can be advanced into the proximal end of the concave region.

46. Regarding the prior art of Fisher, the proximal end of the concave region can receive an electrode along the longitudinal axis passing through the geometric center since both ends of

the concave region (14) are open. It is unclear to the examiner how the fact that the handles are in a single plane is relevant. It is further noted that applicant's forceps tool first regions are connected at their proximal ends (see 200 in fig. 4a of instant application), appear to be in a single plane like those of Fisher, and physically obstruct the concave region eventually just as the rivet (8) of Fisher eventually obstructs the concave region. However, an electrode can be received in the proximal end of the second region from either direction since both ends of the concave region are open (note the space between the rivet and the proximal end of the second region through which an electrode can be inserted and then advanced along the geometric center axis into the concave region).

47. The prior art of Roeschmann has an open distal end on its second region (21) and therefore the concave region (23) is free to receive an electrode along the geometric center of this concave region. For example, an electrode assembly can be inserted into the distal tip of the concave region and moved proximally until it is received in the proximal end of the concave region.

48. Regarding the prior art of Fujitsu et al., applicant argues that the device does not provide operator control over the relative longitudinal movement of the electrode assembly (relative to the forceps tool according to the claim). However, once an electrode assembly is disposed in the concave region (9 inside tube 10), the user may control relative longitudinal movement of the electrode by moving the forceps around to cause sliding of the electrode within the concave region when the electrode is smaller than the area and shorter than the length of the tube (10) housed within the concave region.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 10/22/2008

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731